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**THE DESIGN OF THE ACETABULAR COMPONENT AND SIZE OF THE
FEMORAL HEAD INFLUENCE THE RISK OF REVISION FOLLOWING 34 721
SINGLE-BRAND CEMENTED HIP REPLACEMENTS.
A Retrospective Cohort Study of medium-term data from a National Joint Registry**

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Abstract

Despite excellent results, the use of cemented total hip replacement (THR) is declining. This retrospective cohort study records survival time to revision following primary cemented THR with the commonest brand combination (accounting for almost a quarter of all cemented THRs), exploring risk factors independently associated with failure. All patients with osteoarthritis who had a Stryker Exeter V40/Contemporary THR implanted prior to 31st December 2010 and recorded on the National Joint Registry for England and Wales were included within the analysis. Cox proportional hazard models were used to analyse the extent to which risk of revision was related to patient, surgeon and implant covariates, with a significance threshold of $p < 0.01$. There were a total of 34 721 THRs included in the study. Overall 7-year revision (for any reason) was 1.70%. In the final adjusted model, revision risk was significantly higher in patients implanted with the Contemporary hooded cup (Hazard ratio (HR)=1.88, $p < 0.001$) compared to the flanged version, and in small head sizes ($< 28\text{mm}$, HR=1.50, $p = 0.005$) when compared to 28mm. Seven-year revision was 1.16% with a 28mm head and flanged cup. Overall revision risk was independent of age, sex, ASA grade, BMI, surgeon volume, surgical approach, brand of cement/presence of antibiotic, femoral head material (stainless steel/alumina) and stem taper size/offset. However, the risk of revision for dislocation was significantly higher with a 'plus' offset head (HR=2.05, $p = 0.003$) and hooded cup design (HR=2.34, $p < 0.001$). In summary, we found there were significant differences in implant failure between types of Contemporary cup and femoral component head size after adjustment for a range of covariates.

Introduction

Primary cemented total hip replacement (THR) is a successful operation with good medium- to long-term implant survival across all joint registries and meta-analyses globally (1-7).

Despite their success, the use of cemented THR is declining. Cementless implants are now used in the majority of THRs in the United Kingdom (UK) and Australia (7, 8). In 2005, 54% of 56 350 THRs in England and Wales were cemented. However, during 2010 this had fallen to 36% of 68 907 procedures (7).

National registry data allows independent analyses of large volumes of procedures over an entire population. However, there are limitations to these analyses. Despite the myriad of implant options and materials used, many registries analyse implants using simple discriminators, such as fixation type or bearing surface, when in reality no two brands of implants are alike, and assumptions of similarity may be misplaced.

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single type of cemented THR, using data from the National Joint Registry of England and Wales (NJR) (9). Each brand of implant has a range of parameters that may influence the risk of failure over time. These parameters are not all comparable across brands e.g. design of cup. Thus, to explore the determinants of failure it was appropriate to limit the analysis to the most common cemented brand combination recorded on the NJR (7).

Methods

Design

A retrospective cohort study was conducted using NJR data to assess patient level survival time to revision for the commonest used brand of primary cemented THR, exploring risk factors independently associated with implant failure.

Data

The NJR has assimilated data on patients, surgeons and implants performed in both the private and public sector (National Health Service, NHS) in England and Wales since 2003. According to the NJR 8th Annual Report, the commonest brand combination of cemented THR used in England and Wales since 2003 features the Stryker Exeter V40 hip and Contemporary socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 23.2% of all cemented THRs (37 995 of 163 981) (7). The Exeter V40 femoral stem is a polished, double tapered, collarless stainless steel design with a ‘V40’ taper and a hollow distal centraliser to allow subsidence for compressive loading throughout the cement mantle. It is available in a range of taper sizes (0 to 5), offsets (30mm to 50mm) and lengths (short: 104 to 134mm, standard: 158mm, and ‘long stem’ options: 200mm to 260mm). The monobloc Contemporary cup is manufactured from standard (non cross-linked) Ultra High Molecular Weight Polyethylene (UHMWPE, ‘Duration’) and incorporates four Polymethyl Methacrylate (PMMA) spacer beads on the outer surface to prevent medialisation within the cement mantle. It is available in flanged and hooded varieties, and a range of acetabular (40mm to 60mm) and internal diameter sizes (22mm to 32mm). Femoral heads are available in stainless steel (‘Orthinox’: 22 to 32mm), cobalt-chrome (‘Vitallium’: 28 and 32mm) and ceramic (‘Alumina’ and ‘Delta’ zirconia-alumina: 28 and 32mm). Three brands of cement have been used with these components: ‘Palacos’ (three manufacturers:

Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corporation, Kenilworth, New Jersey, USA; Biomet Inc., Warsaw, Indiana, USA), ‘CMW’ (DePuy Orthopaedics Inc., Warsaw, Indiana, USA) and ‘Simplex’ (Stryker Corporation, Kalamazoo, Michigan, USA). Palacos and CMW are available as high and low viscosity, and all brands have plain or antibiotic impregnated versions. Data were extracted for all Exeter/Contemporary THRs performed and submitted to the NJR until 31st December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in Figure 1.

Covariate categories thought to have an influence on revision risk were patient age at time of procedure, gender, body mass index (BMI), stem size, and head size (10). We also examined the influence of American Society of Anaesthesiology (ASA) grade, head offset and primary surgeon characteristics. Covariates used are summarised in Table 1.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) on the NJR dataset, a complete record of the revision procedure (including side of operation) is submitted from the treating hospital and linked to the original index procedure by matching the unique patient identifier. A number of causes of revision can be recorded for each operation, which were interpreted hierarchically for cause, pre-selecting infection and then peri-prosthetic fracture. Pain was only taken as the primary cause when no other reason was provided.

Statistical analysis

Continuous and discrete continuous covariates (age, head offset, consultant volume) were analysed as categorical data (informed by spread of the data) because of the greater clinical

relevance when making group comparisons. Preliminary analysis of age as a continuous variable was also reported (supplementary material). To explore the influence of covariates the most common category was generally used as the baseline case: for example, 28mm heads were used as the baseline against which all other head sizes were compared. Exceptions to this were age (where the youngest group was used as the baseline) and consultant volume (where the highest volume group was used).

A revision procedure was considered to be a ‘failure event’, where the time between the index primary THR and the revision was the measure of joint survival. Survival times for patients who had not undergone revision were censored at the study census date (31st December 2010). Kaplan-Meier survival charts were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates using the pair-wise over strata method. Covariate categories with unadjusted significant influences are presented, with life tables to describe numbers within each covariate category entering each year of the study.

In order to adjust for differences in known patient, surgeon and implant covariates Cox proportional hazard models were used. The Cox model assumes an underlying baseline risk of revision (hazard) that stays constant through time and is influenced proportionately by covariates, which may mitigate or enhance the risk of revision. Two separate models were constructed: the first for all revisions, and the second for revisions where dislocation was recorded as a reason for revision (other reasons for revision were treated as an alternative outcome - in effect, excluding these from the analysis). Results are presented as Hazard ratios (HRs) with 99% confidence intervals (CI): ratios greater than one indicate that risk is higher when compared with the reference covariate category. Due to the statistical methods

employed, and the large population size, only covariates fitting models with $p < 0.01$ were considered significant influences, to reduce the risk of Type 1 error.

Life tables were produced to report unadjusted one-, three-, five- and seven-year revision rates (with 99% CIs estimated using the normal approximation) for each head size and cup design, and for all 34 721 procedures included in the study. Survival was not reported if number entering a year was less than 5% of the original number entering that particular group.

Results

Of 34 721 primary procedures, the majority were performed in females (22 790, 65.6%), with ASA ≤ 2 (28 747, 82.8%) and 75 years of age or less (18 598, 53.5%); the mean age at implantation was 74 years old. There were 13 797 (39.7%) procedures with complete BMI data; of the procedures with data, the majority were less than 30kg/m² (8929, 64.7%). The majority of stems used 44mm offset (18 161, 52.3%) and the most commonly used taper was size 1 (10 925, 31.5%). The commonest cup design was flanged (24 212, 69.7%) and the commonest head was stainless steel (32 724, 94.2%), 28mm (27 218, 78.4%) with standard offset (22 446, 64.6%). The majority of procedures were performed with high viscosity antibiotic impregnated cement (21 674, 62.4%), and the commonest brand was Palacos HV with antibiotic (20 664, 59.5%). In most cases the consultant performed the procedure (25 962, 74.8%) through an anterolateral approach (17 065, 49.1%), and was a medium- or high-volume surgeon (≥ 51 cases over study period: 25 688, 74.0%).

Patients were under the care of 973 different consultants in 271 different surgical units. Demographics are shown in Table 2. The proportion of flanged cups used increased from 56.2% (470) in 2003 to 71.8% (4339) in 2010. Over the period of the study the use of <28mm heads declined from 56.4% (472) in 2003 to 5.1% (309) in 2010, whilst the use of 28mm heads increased from 43.6% (365) to 79.7% (4812). Thirty-two millimetre heads were used in small numbers from 2004; by 2010 they accounted for 15.2% (919) of the head sizes used (Table 3). In this study, 54.0% (18 746) of procedures were performed with a 28mm head and flanged cup combination.

Reasons for revision

Two hundred and seventy-nine patients had undergone a revision procedure by the census date. The most common reason was dislocation (98 revisions, 35.1% of all revisions). The primary reason for revision was determined to be infection in 72 cases (25.8%), followed by aseptic component loosening/lysis infection (61, 21.9%), malalignment (33, 11.8%) and peri-prosthetic fracture (22, 7.9%). Revision data are summarised in Table 4.

All-cause revision model

In simple (univariable) regression analysis of ‘all revisions’, only cup design influenced implant revision risk ($p < 0.001$) (Figure 2), although there was a trend towards significance in femoral head sizes $< 28\text{mm}$ ($p = 0.022$) (Figure 3, Table 5). Brand of cement was not found to be a significant influence for survival: these covariates were therefore merged into common cement type categories. After risk adjustment, hooded cup design (HR=1.88, 99% CI: 1.38 to 2.57, $p < 0.001$) and head sizes $< 28\text{mm}$ (HR=1.50, 99% CI: 1.03 to 2.17, $p = 0.005$) were independent influences associated with revision. Risk of revision for 32mm head sizes (HR=0.84, 99% CI: 0.36 to 1.94, $p = 0.595$) and ceramic heads (HR=1.10, 99% CI: 0.57 to 2.13, $p = 0.720$) was not significantly different to 28mm and stainless steel heads respectively. Cement viscosity and impregnation with antibiotic did not influence risk of revision (Table 5). Revision risk was independent of gender, age, ASA grade, BMI, stem characteristics, head offset, surgical approach and consultant experience.

Revision for dislocation model

Revisions performed due to dislocation were then analysed. Using simple (univariable) regression analysis, cup design ($p < 0.001$) and ‘plus’ head offsets ($p = 0.003$) influenced implant revision risk (Table 6). After risk adjustment, cup design (HR=2.34, 99% CI: 1.38 to

3.96, $p<0.001$) and plus head offset (HR=2.05, 99% CI: 1.10 to 3.80, $p=0.003$) remained significant influences on risk of revision.

Revision rates

The overall seven-year revision rate was 1.70% (99% CI 1.28 to 2.12) for the entire study population (Table 7). Seven-year revision rates were lowest with 28mm heads and flanged cups (1.16%, 99% CI 0.69 to 1.63). A head size <28mm used together with a hooded cup resulted in a 7-year revision rate of 3.49% (99% CI 1.50 to 5.48). Although 32mm heads have only been used in the last four years, early (3-year) revision for hip replacements with flanged cups (0.53%, 99% CI 0.00 to 1.17) was similar to 28mm heads and flanged cups (0.67%, 99% CI 0.49 to 0.86).

Discussion

This retrospective cohort study provides the largest, in-depth analysis of a single brand combination of cemented THRs to date. Significantly greater revision rates following THR were independently associated with a hooded cup design and small femoral head sizes (<28mm), after risk adjustment. These findings are clinically important as they identify modifiable parameters in the control of the operating surgeon. Other implant factors, including surgical approach, femoral head material and type of cement used, did not significantly influence revision.

Whilst these data are the largest to date reporting a single brand combination analysis, we accept that there are limitations in its interpretation. The revision rates described in this study are limited to mid-term data only (the earliest implant was in 2003). The relative rates at which particular implants require revision may change with further follow-up and more informative data. Revision is taken as a surrogate marker of implant failure, as other endpoints are unavailable. This does not take into account patients living with a painful hip, or those awaiting revision at the time of censoring (11). Information regarding duration and severity of symptoms, radiographic appearance and activity levels prior to and following the procedure were not available in the NJR data. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. For example, registries may not capture all the issues driving component selection; higher revision may be a result of unmeasured patient or surgical factors rather than specific component factors. Despite these limitations, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

The hooded Contemporary cup option was found to be associated with a significantly higher risk of revision for all causes and revision when dislocation was the cause. Two main design differences distinguish the hooded cups from the flanged: the hooded cup incorporates a large posterior elevation (or hood) with the intention of reducing the risk of dislocation, and the flanged cup incorporates a wide circumferential rim of polyethylene (the flange) that can be trimmed by the surgeon to enclose the acetabulum, thereby preventing cement escape during pressurisation. This outer rim, together with the absence of the posterior hood, may allow easier cup positioning. The hood may also (paradoxically) increase the risk of dislocation, by allowing the implant neck to impinge on the hood and pivot the head anteriorly out from the cup. Within the thresholds set for covariates, there is no evidence from this study to suggest the influence of cup design was related to surgeon experience, head offset or surgical approach. Although the NJR reports revision for Contemporary cups as one group (7), the Orthopaedic Device Evaluation Panel (ODEP) has recommended that revision be divided by hooded and flanged types (12). The findings of this current study support the ODEP recommendation.

Data from the Swedish arthroplasty register have previously demonstrated that an Exeter stem with head size of 22mm has a significantly higher revision rate than 28mm ($p=0.004$) in over 21000 THRs (13). Although the majority of smaller heads in this current study were sized 26mm, the findings were similar. The benefit of 32mm has yet to be established.

A 'plus' offset head was also a significant influence for risk of revision for dislocation. This may reflect a failure to adequately restore offset with the stem options available, or a perception of instability from the operating surgeon at the time of trialling with a standard head following stem implantation. Although this covariate did not have a significant

influence on the all-cause revision model, this should be considered when selecting the most appropriate femoral stem and head offset.

In the most recent NJR AR (8th) brand specific analyses are reported up to five years only. For 37 995 Exeter V40/Contemporary THRs five year revision was 1.26% (95% CI 1.10 to 1.44) (7). As expected, the overall revision presented in this current study at five years was similar (1.26%, 99% CI 1.03 to 1.48). However, revision at five years when a 28mm head was used in combination with a flanged cup was only 0.85% (99% CI 0.60 to 1.10).

Although in 2010 the majority of components used were 28mm heads (78.4%) with flanged cups (69.7%), only 54.0% of procedures employed this combination over the entire study. Overall revision, as described in the analyses of brands in the NJR 8th Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of smaller head sizes and hooded cups). Components that are now most commonly used in current practice have lower revision rates than those reported by the NJR.

Risk of revision was independent of age and gender, despite previous reports of poorer outcomes in young, male patients after cemented THR (10, 14). Contrasting with cementless THR, BMI $\geq 30\text{kg/m}^2$ and higher ASA were not significant influences of failure (10, 15). It is possible that failure to fit BMI within models may be due to only 39.7% of records including BMI data, emphasising the importance of efforts to improve BMI recording to allow for appropriate adjustment in future explanatory analysis. Increasing femoral head size is thought to contribute to lower dislocation (16) and revision (17). However, in this study, revision of the larger head size (32mm) was similar to 28mm, although longer-term analyses are needed as 32mm heads have a shorter follow-up. Of note, surgical approach did not

influence all cause revision nor revision for dislocation, after adjustment for other factors. Cement brand, viscosity and presence of antibiotic also failed to influence risk of revision.

The commonest primary reason for revision was dislocation (35.1%); infection accounted for only 25.8% of revisions. This study reports mid-term data: as expected, only a small number of implants (21.9%) were revised for aseptic loosening/lysis.

In summary, there were significant differences in implant failure between types of cup design and femoral head sizes after adjustment for a range of covariates in a large cohort of single-brand cemented THRs. In this study, hooded Contemporary cups and femoral head sizes <28mm had significantly higher revision rates. In terms of revision for dislocation, a 'plus' offset femoral head is significantly associated with increased risk. This study demonstrates that multiple factors can influence revision risk; registry data analyses may mislead if they fail to adjust for all relevant covariates when comparing across brands and types. For surgeons using cemented THR, the findings presented may help guide their practice. Findings may also provide a useful reference for comparison with future analyses comparing implant types.

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Conflict of Interests Statement

The National Joint Registry for England and Wales is funded through a levy raised on the sale of hip and knee replacement implants. The cost of the levy is set by the NJR Steering Committee. The NJR Steering Committee is responsible for data collection. This work was

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. Morshed S, Bozic KJ, Ries MD, Malchau H, Colford JM, Jr. Comparison of cemented and uncemented fixation in total hip replacement: a meta-analysis. *Acta Orthop*. 2007 Jun;78(3):315-26.
2. No-authors-listed. Annual Report 2008, 8 year report. New Zealand National Joint Registry. 2008 [23/03/2012]; Available from: <http://www.cdhb.govt.nz/njr/reports/A2D65CA3.pdf>.
3. No-authors-listed. Annual Report 2006. Finnish National Arthroplasty Register. 2006; Available from: <http://www.nam.fi/english/publications>.
4. No-authors-listed. Annual Report 2008. Norwegian Arthroplasty Register. 2008 [23/03/2012]; Available from: <http://www.haukeland.no/nrl/eng/default.htm>.
5. No-authors-listed. Annual report 2010. Swedish Hip Registry. 2010; Available from: <http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sflb.ashx>.
6. Corbett KL, Losina E, Nti AA, Prokopetz JJ, Katz JN. Population-based rates of revision of primary total hip arthroplasty: a systematic review. *PLoS One*. 2010;5(10):e13520.
7. No-authors-listed. National Joint Registry for England and Wales 8th Annual Report. 2011 [25/03/2012]; Available from: <http://www.njrcentre.org.uk/NjrCentre/LinkClick.aspx?fileticket=1TQ%2bEiNejm0%3d&tabid=86&mid=523>.
8. No-authors-listed. Australian Orthopaedic Association, National Joint Replacement Register. . 2010 [13th June 2011]; Available from: <http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp>
9. No-authors-listed. National Joint Registry for England and Wales. 2012 [02/04/2012]; Available from: <http://www.njrcentre.org.uk/njrcentre/default.aspx>.
10. Roder C, Bach B, Berry DJ, Eggli S, Langenhahn R, Busato A. Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case-control study of 4420 patients. *J Bone Joint Surg Am*. 2010 Aug 18;92(10):1954-63.
11. Wylde V, Blom AW. The failure of survivorship. *J Bone Joint Surg Br*. 2011 May;93(5):569-70.
12. No-authors-listed. Orthopaedic Device Evaluation Panel. 2012 [02/04/2012]; Available from: <http://www.supplychain.nhs.uk/odep/>.

13. Thien TM, Karrholm J. Design-related risk factors for revision of primary cemented stems. *Acta Orthop*. 2010 Aug;81(4):407-12.
14. Chandler HP, Reineck FT, Wixson RL, McCarthy JC. Total hip replacement in patients younger than thirty years old. A five-year follow-up study. *J Bone Joint Surg Am*. 1981 Dec;63(9):1426-34.
15. Jameson SS BP, Rymaszewska M, Mason J, Gregg PJ, Deehan DJ, Reed MR. Higher revision with hard bearings following 35 386 single-brand cementless hip replacements - A Retrospective Cohort Study using National Joint Registry Data. *J Bone Joint Surg Br* (Proceedings, in press). 2012.
16. Jameson SS, Lees D, James P, Serrano-Pedraza I, Partington PF, Muller SD, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. *J Bone Joint Surg Br*. 2011 Jul;93(7):876-80.
17. Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. *Lancet*. 2012 Mar 12.

Figure 1. Flow chart describing the procedures included

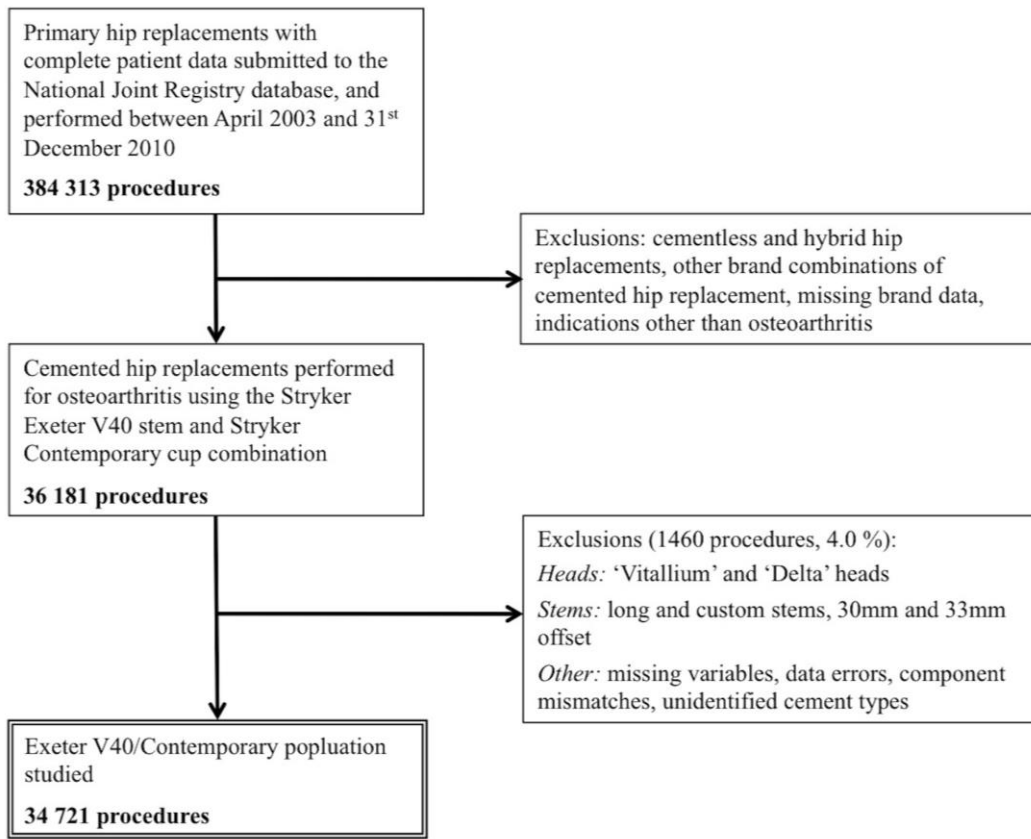
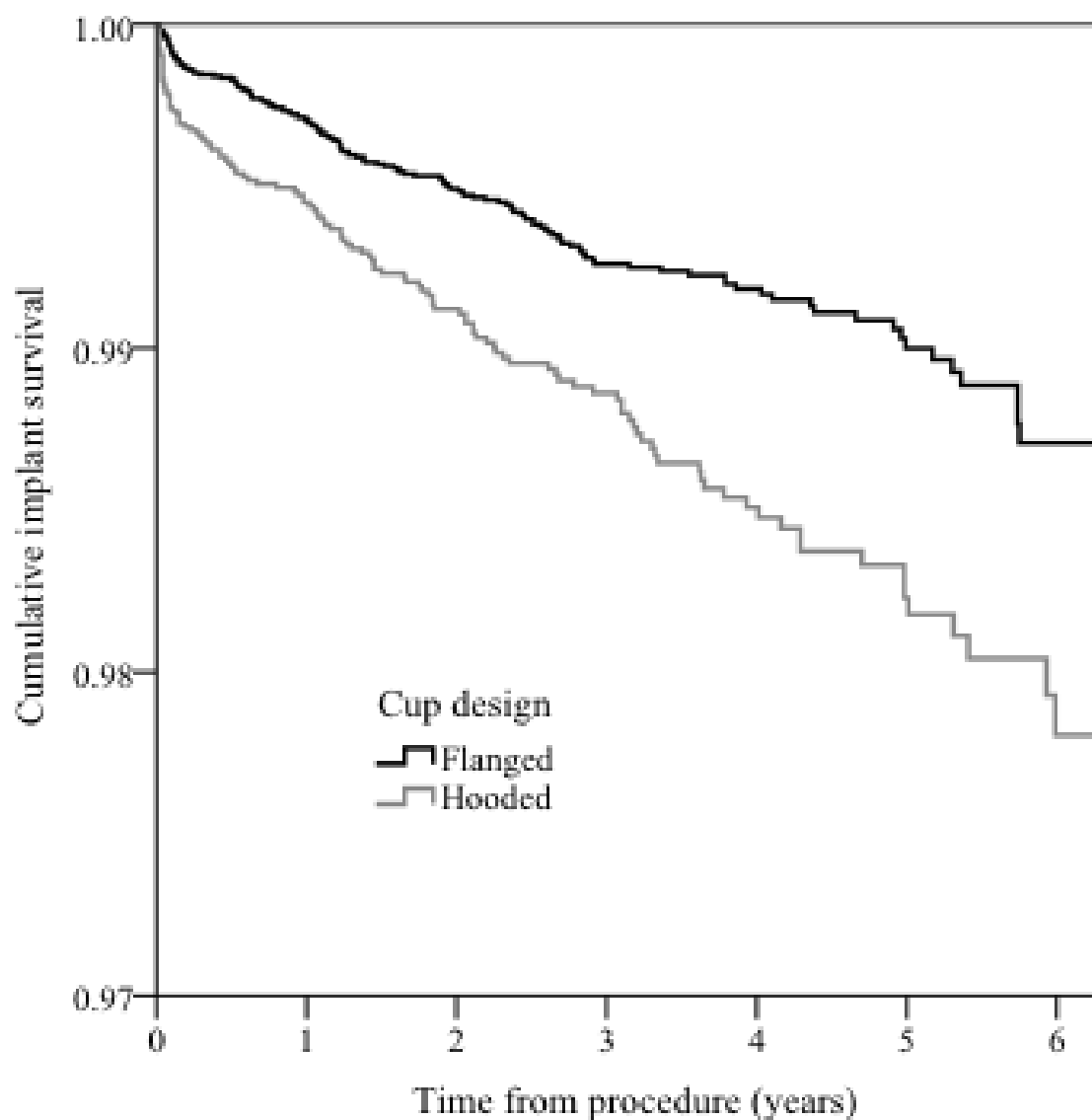


Figure 2. Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Contemporary by cup design (England and Wales, 2003-2010)

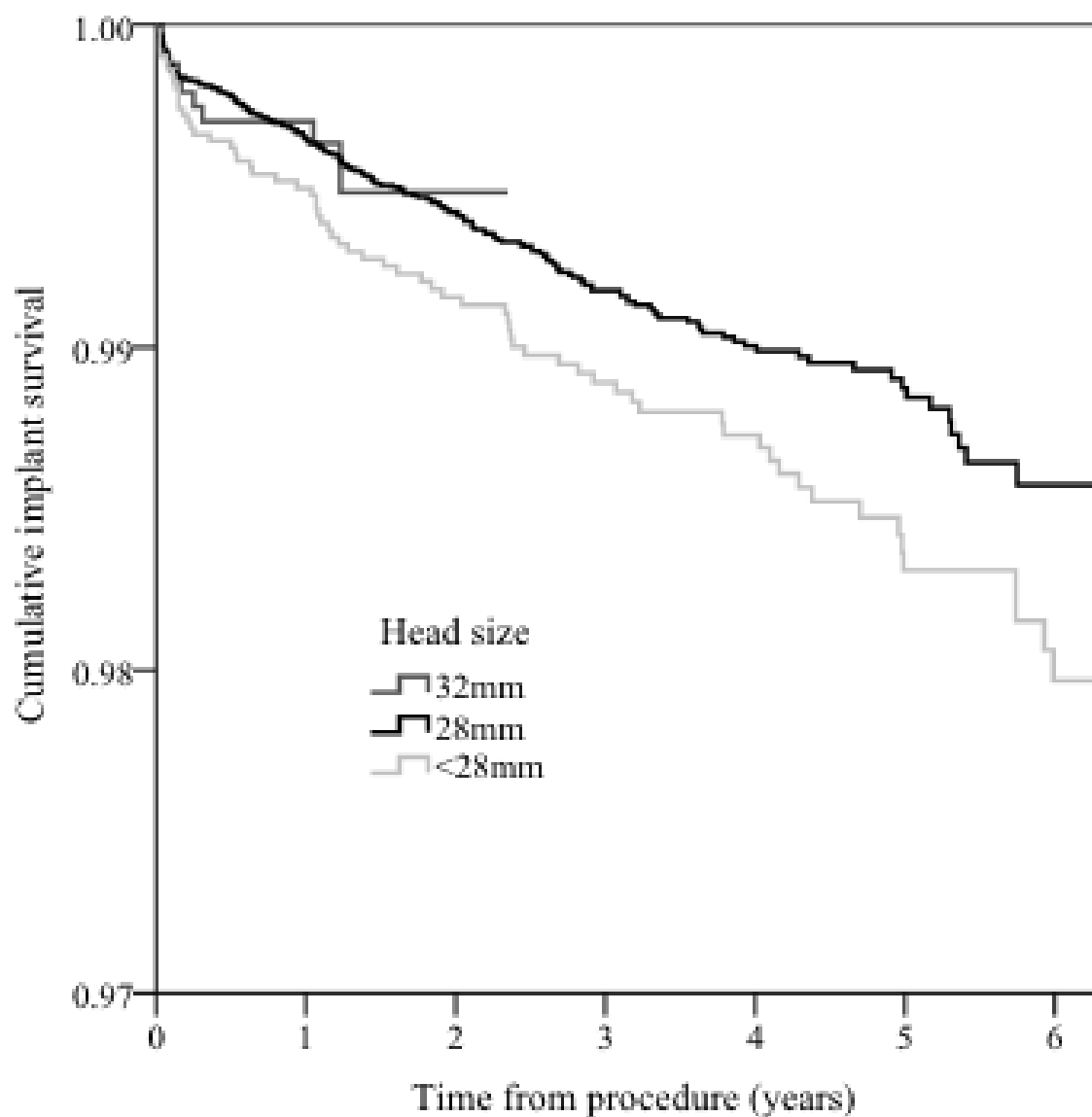


Log rank (Mantel-Cox)	Flanged	Hooded
Flanged (p-value)	-	<0.001
Hooded	<0.001	-

Life table showing numbers at risk in each year

Cup design	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Flanged	24212	19491	14795	10276	6176	3282	1281	375
Hooded	10509	8582	6793	4846	3176	1913	790	283

Figure 3. Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Contemporary by head size (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	<28mm	28mm	32mm
<28mm (p-value)	-	0.022	0.101
28mm	0.022	-	0.615
32mm	0.101	0.615	-

Life table showing numbers at risk each year

Femoral size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
<28mm	5036	4619	4032	3365	2547	1783	1034	378
28mm	27218	21946	16873	11482	6691	3374	1031	280
32mm	2467	1508	683	275	114	38	6	0

Table 1. Covariates used in the event analyses

Category	Variable type	Covariate
Age	Ordinal	≤ 60 years, 61-75, ≥ 76
Gender	Binary	Female, Male
ASA grade	Ordinal	Grade ≤ 2 , Grade ≥ 3
Body mass index	Ordinal	$< 30 \text{ kg/m}^2$, $\geq 30 \text{ kg/m}^2$
Stem offset	Ordinal	35mm, 37.5mm, 44mm, 50mm
Stem taper	Ordinal	0, 1, 2, 3, ≥ 4
Head size	Ordinal	< 28 , 28mm, 32mm
Head offset	Ordinal	Standard, 'Plus' head, 'Minus' head
Cup design	Nominal	Flanged, Hooded
Bearing	Nominal	Metal-on-polyethylene, Ceramic-on-polyethylene
Cement type	Nominal	High viscosity antibiotic impregnated <i>Palacos HV, CMW HV</i>
		Low viscosity antibiotic impregnated <i>Simplex LV, Other (Palacos LV, CMW LV)</i>
		High viscosity, no antibiotic <i>Palacos HV, CMW HV</i>
		Low viscosity, no antibiotic <i>Simplex LV, Other (CMW LV, Palacos LV)</i>
Surgical approach	Nominal	Anterolateral, Posterior, Other
Primary surgeon	Binary	Consultant, Other
Consultant volume	Ordinal	Low (≤ 50 cases throughout study period), Medium (51-300), High (≥ 301)

ASA – American Society of Anaesthesiologists, BMI – body mass index, kg – kilogram, m – metre, mm – millimetre

Table 2. Demographics of Exeter V40/Contemporary cemented hip replacements (England and Wales, 2003-2010)

	n=34 721
<i>Age</i> , mean years (SD, range)	73.9 (8.0, 23-100)
≤60, n (%)	1603 (4.6)
61-75	16 965 (48.9)
≥76	16 153 (46.5)
<i>Gender</i>	
Female	22 790 (65.6)
Male	11 931 (34.4)
<i>ASA grade</i>	
1/2	28 747 (82.8)
≥3	5974 (17.2)
<i>Body mass index</i> , mean kg/m ² (SD)	28.2 (5.1)*
<30kg/m ² , n (%)	8929 (25.7)
≥30kg/m ²	4868 (14.0)
No data	20 924 (60.3)
<i>Stem offset</i>	
35mm	1690 (4.9)
37.5mm	13 449 (38.7)
44mm	18 161 (52.3)
50mm	1421 (4.1)
<i>Stem taper</i>	
0	10 656 (30.7)
1	10 925 (31.5)
2	8770 (25.3)
3	3227 (9.3)
≥4	1143 (3.3)
<i>Head size</i>	
<28mm	5036 (14.5)
22mm	104 (0.3)
26mm	4932 (14.2)
28mm	27 218 (78.4)
32mm	2467 (7.1)
<i>Head offset</i>	
Standard (0)	22 446 (64.6)
Plus (+2mm to +12mm)	5686 (16.4)
Minus (-2mm to -4mm)	6589 (19.0)
<i>Cup design</i>	
Flanged	24 212 (69.7)
Hooded	10 509 (30.3)
<i>Bearing</i>	
Metal-on-polyethylene	32724 (94.2)
Ceramic-on-polyethylene	1997 (5.8)
<i>Cement</i>	
High viscosity antibiotic impregnated	21 674 (62.4)
Palacos HV	20 664 (59.5)
CMW HV	1011 (2.9)
Low viscosity antibiotic impregnated	8561 (24.7)
Simplex LV	8280 (23.8)
Other (Palacos LV, CMW LV)	281 (0.8)
High viscosity, no antibiotic	1426 (4.1)
Palacos HV	831 (2.4)
CMW HV	595 (1.7)
Low viscosity, no antibiotic	1570 (4.5)
Simplex LV	1567 (4.5)
Other (CMW LV, Palacos LV)	3 (0.0)
Missing	1490 (4.3)

<i>Surgical approach</i>		
Anterolateral	17 065	(49.1)
Posterior	15 386	(44.3)
Other	1067	(3.1)
Missing data	1203	(3.5)
<i>Primary surgeon</i>		
Consultant	25 962	(74.8)
Other	8759	(25.2)
<i>Number of consultants (n)</i>	973	
<i>Consultant volume</i>		
Low (≤ 50 cases over study period)	9033	(26.0)
Medium (51-250)	15 978	(46.0)
High (≥ 251)	9710	(28.0)
<i>Number of surgical units (n)</i>	271	

SD – standard deviation, * - based on 13 797 procedures

Table 3. Proportion of cup designs and head sizes used by year (England and Wales, 2003-2010)

Year	Cup design		Head size		
	Flanged	Hooded	<28mm	28mm	32mm
2003, n (%)	470 (56.2)	367 (43.8)	472 (56.4)	365 (43.6)	0 (0.0)
2004	1038 (63.4)	599 (36.6)	745 (45.5)	884 (54.0)	8 (0.5)
2005	2273 (64.6)	1243 (35.4)	839 (23.9)	2642 (75.1)	35 (1.0)
2006	3045 (69.9)	1327 (30.4)	779 (17.8)	3507 (80.2)	86 (2.0)
2007	4168 (71.0)	1702 (29.0)	788 (13.4)	4916 (83.7)	166 (2.8)
2008	4402 (69.8)	1904 (30.2)	599 (9.5)	5270 (83.6)	437 (6.9)
2009	4477 (72.9)	1666 (27.1)	505 (8.2)	4822 (78.5)	816 (13.3)
2010	4339 (71.8)	1701 (28.2)	309 (5.1)	4812 (79.7)	919 (15.2)
<i>Total</i>	<i>24 212 (69.7)</i>	<i>10 509 (30.3)</i>	<i>5036 (14.5)</i>	<i>27 218 (78.4)</i>	<i>2467 (7.1)</i>

Table 4. Reasons recorded for revision following Exeter V40/Contemporary cemented hip replacement (England and Wales, 2003-2010)

	Revision (n=279)
Dislocation, n (%)	98 (35.1)
Infection	72 (25.8)
All aseptic component loosening/lysis	61 (21.9)
<i>Stem only</i>	19 (6.8)
<i>Cup only</i>	41 (14.7)
<i>Both</i>	1 (0.4)
All malalignments	33 (11.8)
<i>Stem only</i>	5 (1.8)
<i>Cup only</i>	23 (8.2)
<i>Both</i>	5 (1.8)
Periprosthetic fracture	22 (7.9)
<i>Stem only</i>	20 (7.2)
<i>Cup only</i>	2 (0.7)
Unexplained pain	9 (3.2)
Polyethylene cup wear	8 (2.9)
All implant fractures	4 (1.4)
<i>Stem only</i>	2 (0.7)
<i>Cup only</i>	2 (0.7)
Other	28 (6.3)

Table 5. Independent predictors of all revisions following 34 721 cemented Exeter/Contemporary hip replacements: simple and multiple variable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis		
	HR	99% CI	P value	HR	99% CI	P value
<i>Gender</i>						
Female	1					
Male	1.22	0.89-1.67	0.112			
<i>Age</i>						
Category			0.086			
≤60	1					
61-75	0.81	0.43-1.51	0.373			
≥76	0.64	0.34-1.22	0.075			
<i>ASA grade</i>						
1/2	1					
≥3	0.97	0.63-1.50	0.869			
<i>Body mass index</i>						
<30kg/m ²	1					
≥30kg/m ²	1.61	0.66-2.05	0.500			
<i>Stem offset</i>						
Category			0.580			
35mm	1.11	0.53-2.34	0.719			
37.5mm	1.16	0.84-1.60	0.237			
44mm	1					
50mm	0.83	0.34-2.02	0.598			
<i>Stem taper</i>						
Category			0.586			
0	1.07	0.73-1.57	0.655			
1	1					
2	0.82	0.54-1.25	0.231			
3	0.90	0.51-1.59	0.630			
≥4	0.90	0.37-2.21	0.764			
<i>Head size</i>						
Category			0.055			0.009
<28mm	1.38	0.96-1.99	0.022	1.50	1.03-2.17	0.005
28mm	1			1		
32mm	0.84	0.36-1.94	0.595	0.76	0.33-1.75	0.391
<i>Head offset</i>						
Category			0.452			
Standard	1					
Plus	1.13	0.74-1.73	0.445			
Minus	1.19	0.81-1.76	0.249			
<i>Bearing</i>						
Metal-on-poly.	1					
Ceramic-on-poly.	1.10	0.57-2.13	0.720			
<i>Cup design</i>						
Flanged	1			1		
Hooded	1.79	1.32-2.45	<0.001	1.88	1.38-2.57	<0.001
<i>Cement</i>						
Category			0.807			
HV antibiotic	1					
LV antibiotic	1.09	0.77-1.54	0.546			
HV, no antibiotic	0.83	0.35-1.89	0.530			
LV, no antibiotic	0.93	0.44-1.96	0.809			
<i>Surgical approach</i>						
Category			0.226			
Anterolateral	1					
Posterior	0.84	0.60-1.17	0.172			
Other	1.33	1.33-3.23	0.410			

<i>Operator</i>			
Consultant	1		
Other	0.96	0.67-1.38	0.779
<i>Consultant volume</i>			
Category			0.137
Low (≤ 50)	1.39	0.91-2.11	0.046
Medium (51-300)	1.18	0.81-1.74	0.257
High (≥ 301)	1		

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists

Table 6. Independent predictors of revision for dislocation: simple and multiple variable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis		
	HR	99% CI	P value	HR	99% CI	P value
<i>Gender</i>						
Female	1					
Male	1.14	0.65-2.02	0.541			
<i>Age</i>						
Category			0.371			
≤60	1					
61-75	2.61	0.41-16.69	0.183			
≥76	2.29	0.36-14.81	0.252			
<i>ASA grade</i>						
1/2	1					
≥3	1.23	0.63-2.42	0.422			
<i>Body mass index</i>						
<30kg/m ²	1					
≥30kg/m ²	0.54	0.21-1.44	0.107			
<i>Stem offset</i>						
Category			0.305			
35mm	1.91	0.67-5.46	0.112			
37.5mm	1.36	0.78-2.39	0.153			
44mm	1					
50mm	1.21	0.32-4.65	0.715			
<i>Stem taper</i>						
Category			0.607			
0	1.23	0.64-2.37	0.421			
1	1					
2	0.85	0.40-1.79	0.566			
3	1.00	0.38-2.68	0.991			
≥4	1.61	0.46-5.60	0.327			
<i>Head size</i>						
Category			0.349			
<28mm	1.43	0.76-2.68	0.147			
28mm	1					
32mm	1.11	0.33-3.66	0.830			
<i>Head offset</i>						
Category			0.014			0.010
Standard	1			1		
Plus	2.02	1.09-3.75	0.003	2.05	1.10-3.80	0.003
Minus	1.20	0.59-2.42	0.512	1.09	0.54-2.20	0.762
<i>Bearing</i>						
Metal-on-poly.	1					
Ceramic-on-poly.	1.18	0.40-3.49	0.701			
<i>Cup design</i>						
Flanged	1			1		
Hooded	2.30	1.36-3.90	<0.001	2.34	1.38-3.96	<0.001
<i>Cement</i>						
Category			0.420			
HV antibiotic	1					
LV antibiotic	1.18	0.66-2.11	0.468			
HV, no antibiotic	0.24	0.02-3.25	0.159			
LV, no antibiotic	0.86	0.23-3.27	0.773			
<i>Surgical approach</i>						
Category			0.141			
Anterolateral	1					
Posterior	1.53	0.87-2.66	0.051			
Other	1.54	0.33-7.26	0.470			
<i>Operator</i>						

Consultant	1		
Other	0.86	0.46-1.63	0.546
<i>Consultant volume</i>			
Category			0.266
Low (≤ 50)	1.58	0.76-3.31	0.110
Medium (51-300)	1.39	0.70-2.73	0.216
High (≥ 301)	1		

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists

Table 7. Revision rates following Exeter/Contemporary hip replacement by head size and cup design (99% confidence intervals) (England and Wales, 2003-2010)

	Revision rates by head size			Overall revision rates
	<28mm	28mm	32mm	
1-year				
All	0.52% (0.25-0.78)	0.36% (0.26-0.46)	0.35% (0.01-0.69)	0.38% (0.29-0.47)
Flanged	0.41% (0.15-0.68)	0.27% (0.17-0.38)	0.35% (0.00-0.80)	0.30% (0.21-0.40)
Hooded	0.92% (0.13-1.71)	0.55% (0.34-0.77)	0.35% (0.00-0.88)	0.57% (0.38-0.77)
3-year				
All	1.13% (0.72-1.54)	0.84% (0.67-1.01)	0.62% (0.09-1.15)	0.88% (0.73-1.04)
Flanged	1.07% (0.62-1.52)	0.67% (0.49-0.86)	0.53% (0.00-1.17)	0.75% (0.58-0.92)
Hooded	1.38% (0.40-2.35)	1.20% (0.85-1.56)	0.73% (0.00-1.58)	1.18% (0.87-1.50)
5-year				
All	1.71% (1.13-2.28)	1.13% (0.90-1.37)	0.62% (0.09-1.15)	1.26% (1.03-1.48)
Flanged	1.42% (0.84-2.01)	0.85% (0.60-1.10)	- -	0.99% (0.75-1.23)
Hooded	2.63% (1.13-4.12)	1.71% (1.21-2.21)	0.73% (0.00-1.58)	1.82% (1.35-2.30)
7-year				
All	2.12% (1.36-2.89)	1.60% (1.05-2.15)	- -	1.70% (1.28-2.12)
Flanged	1.62% (0.93-2.31)	1.16% (0.69-1.63)	- -	1.25% (0.89-1.62)
Hooded	3.49% (1.50-5.48)	2.37% (1.25-3.48)	- -	2.55% (1.63-3.46)
Total number				
All	5036	27218	2467	34 721
Flanged	4024	18 746	1442	24 212
Hooded	1012	8472	1025	10 509

Supplementary material

The reliability of the statistical models was explored in a number of ways: covariates found not to be statistically significant were excluded from the model, based on statistical entry ($p < 0.05$) and rejection ($p > 0.10$) criteria; the same covariates were fitted forward and reverse stepwise (likelihood ratio test) to ensure findings were not qualitatively affected in the final model, with any inconsistency reported; the final models were re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring 2-way interactions between covariates and for the constant proportionality over time assumption. In addition, baseline entry and rejection criteria for the models were reduced to $p < 0.01$ and $p > 0.05$ respectively to test covariate selection within the models. In order to improve efficiency of the final models, where no differences were found within subcategories (e.g. different cement brands) during preliminary modelling, a decision was taken to combine these. All models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, New York).

When age was considered as a continuous variable, in the adjusted model there was a trend towards significance (HR=0.98, 99% CI 0.96 to 1.00, $p=0.013$), but this did not affect selection within the model nor the influence of the significant covariates (hooded cup: HR=1.89, head size <28mm: HR=1.47). The final model was therefore reported with age as a categorical covariate. Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models for all-cause revision and revision for dislocation.